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Original Research Article

An assessment of storage practices of essential medicines in primary health centers of Gadag taluk, Karnataka

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ABSTRACT

Background: The efficacy and safety of medications may be impacted by the potency loss that occurs during storage. Pharmaceuticals need to be stored under controlled conditions and transportation situations to make sure its quality isn't harmed. A crucial component of the overall drug control system is storage. Wherever pharmaceuticals and supplies are kept on the property, sufficient environmental control must be maintained, including the right temperature, light, and humidity levels, as well as sanitary, ventilation, and segregation requirements.
Methods: A cross sectional study was done to assess the Storage conditions of medicines in pharmacies of primary health centers of Gadag Taluk. Storage facilities was assessed using observational checklist. Sampling design was universal sample all 15 primary health centers (PHCs) as per health management information system (HMIS) data was assessed for Storage conditions of essential medicine in primary health centre.
Results: Results indicate that storage conditions for essential medicines are: 80% of pharmacies have a dedicated warehouse or storage space for drugs; 100% have a method to control temperature; 93.33% have cold storage facilities; 100% use racks; only 33.3% have drugs arranged with identification labels; manufacturing dates and expiration dates are clearly visible; and medicines are stored in a systemic way.
Conclusions: In summary, the primary health centre's pharmacies are generally storing medications correctly, but there is room for improvement. Labelling drugs, managing expired drugs, and training staff can help improve storage and drug supply. These measures can ensure better medication storage conditions.

Keywords: Drug, Essential medicines, Quality, PHC, Storage

INTRODUCTION

Pharmaceutical companies consider several standards while developing new drugs, including dosage, administration method, side effects, safety, effects of an overdose, and efficacy. To determine how these medications should be stored, they also put a lot of effort into researching how the environment affects them.[1] Therefore, different drugs have varied manufacturer guidelines or storage criteria. For instance, some must be frozen, others must be refrigerated, and some must be kept at room temperature. Regardless of its size or capacity, every pharmacy must effectively store medications. If exposed to various environmental factors, improper storage might affect the efficacy and potency of drugs.[2] If such medications are consumed, customers may run the risk of developing health problems. Basically, different climatic factors like temperature, humidity, and sunshine affect how well drugs are stored.[2] The code of ethics states that chemists are required to make sure their facilities are equipped with the right tools for storing medications with various temperature, moisture, and sunlight requirements.[3] Additionally, the Food and Drug Administration (FDA) regulations state in section

2111.166 of 21CFR205.50 that all medications must be maintained in accordance with the specifications of the manufacturer and at the proper temperatures and humidity levels.[4] The medication should be kept in a controlled environment with enough ventilation and light unless the manufacturer has instructed otherwise.[5]

The quality and efficacy of pharmaceutical products depend greatly on storage conditions.[6] This is especially true for medicines, which are sensitive to temperature and humidity, making it important to store them in a safe and controlled environment, preferably according to predetermined guidelines. Primary health centers (PHCs) must adhere to these standards to protect the health and safety of their patients as well as guarantee optimal medication therapy.[7] The three studies conducted in North Indian states (Punjab and Haryana), Odisha, and Karnataka concluded that in Punjab and Haryana, 95% of the public health facilities in Punjab had dedicated storage spaces with temperature control and proper ventilation, and 85% of facilities had cold storage facilities.[8-10] In Haryana, all public health facilities had dedicated storage with temperature control and cold storage, though evidence of pests was found in 10% of facilities. The study in Odisha revealed that the storage conditions of drugs were found to be poor, and the study in Karnataka concluded that the condition of the pharmacy infrastructure deteriorated as the location moved away from city limits. These studies demonstrate that in both rural and urban areas of North India and South India, the public health infrastructure is inadequate and that steps must be taken to improve the quality of medication storage. In addition, the detection of pests in drug storage facilities suggests that more rigorous hygiene standards must be adopted and that more vigilant monitoring of pharmaceutical stores is needed. Poor management techniques and insufficient storage settings for medications whose quality is impacted by light, humidity, ventilation, temperature, and hygienic conditions, as well as inadequate storage infrastructure, are some of the factors causing a lack of medicines.[11] Proper storage conditions for medicines play a vital role in the effective management of public health and medicine safety in a primary health care (PHC) setting.[12] The quality and efficacy of medicines are largely dependent on how they are stored and maintained.[13] Unsuitable or unsafe storage conditions can reduce their therapeutic value, cause them to deteriorate, and render them potentially harmful.[14] In a PHC center, the storage conditions of medicines are closely related to proper medication usage and the effectiveness of cost-effective pharmaceutical care. For this reason, predetermined storage conditions are set in a PHC setting for each type of medicine to guarantee their safety in delivering optimal medication therapy.[15] So, the main aim of the current study is to assess the storage conditions of medicines in pharmacies of primary health centers in Gadag taluk, Karnataka.

METHODS

Study design

A cross-sectional research study was undertaken to assess the storage conditions of medicines within the primary health centers situated in Gadag Taluk, Karnataka. The primary objective of this study was to assess and analyse the prevailing storage conditions to ensure the optimal preservation of pharmaceutical products. By employing a cross-sectional design, data was collected at a single point in time, allowing for a snapshot of the storage conditions across the primary health centers. The study aimed to identify potential shortcomings, deficiencies, and areas for improvement in the storage practices employed, ultimately contributing towards enhancing the overall quality and efficacy of pharmaceutical services provided in the region.

Study setting and duration

This study was conducted within the geographic region of Gadag Taluk, situated in the Gadag District of Karnataka, India. The data collection and analysis took place over a period spanning from November 2021 to March 2022.

Sample size of the study

The sampling size for this study was based on the list of primary health centers (PHCs) provided by Karnataka's Health Management Information System, which serves as a comprehensive database of healthcare facilities in the state. In accordance with this list, all 15 primary health centers located within Gadag Taluk were selected as the target sample for this research. By including all the PHCs in the region, a representative and inclusive assessment of the storage conditions of medicines in the primary healthcare setting was ensured.

Data collection tools

To gather quantitative data on storage conditions for this study, an observation checklist was developed after conducting a comprehensive review of previous relevant studies. This checklist was meticulously designed to assess specific parameters and indicators related to storage conditions of medicines in primary health centers. The checklist incorporated validated and standardized criteria, which were adapted and tailored to suit the specific context of the study in Gadag Taluk.

Data collection

To make sure that data collecting was practical, a pilot study was done. To prevent bias, the checklist was kept secret. On the day of the survey, the pharmacies of the health facilities were observed directly in the presence of pharmacists and medical officers to get data on the Storage conditions of medicines in pharmacies of Primary health centers of Gadag taluk.

Data analysis

The collected quantitative data was processed using Microsoft Excel 2019, enabling the creation of frequency distributions, percentage calculations, and graphical representations. This facilitated a comprehensive analysis and visualization of the data, aiding in the interpretation and presentation of the findings.

RESULTS

The results of the current study show that 80% of pharmacies have a dedicated warehouse or storage space for drugs. 93.33% of pharmacies have cold storage facilities. 100% of pharmacies' usage of racks was observed to store drugs. However, only in 33.3% of facilities were drugs on the shelves arranged with identification labels. In almost 66.67% of pharmacies, drugs on the shelves were not arranged with identification labels. At 100% of pharmacies, manufacturing dates and expiration dates were clearly visible in drug cartons. Only 40% of pharmacies had separate sections for expired drugs. In 86.67% of pharmacies, the storeroom is clean, and in 100% of pharmacies, there is no evidence of rodents, insects, or pests. The storage conditions of essential medicines in primary health care centers in Gadag Taluk are shown in Table 1.

According to the results, none of the medicines were stored directly on the floor; all the medicines were stored on racks of 15 (100). Only six (40.00) had a separate compartment for expired drugs. The arrangement of medicines on the shelves of the storage room is shown in Table 2.

Table 1: Storage condition of essential medicines at pharmacies of PHCS (n= 15).

Indicators	Yes	No
	N (%)	N (%)
Do they have a dedicated warehouse or storage space for drugs?	12 (80.00)	3 (20.00)
Is there a method in place to control temperature, e.g., air conditioners, fans, etc.?	15 (100.00)	0 (0.00)
Are there windows that can be opened, or are there air vents?	15 (100.00)	0 (0.00)
Is there cold storage in the facility?	14 (93.33)	1 (6.67)
There is no evidence of food or drinks in the storage area.	15 (100.00)	0 (0.00)
The storeroom is clean.	13 (86.67)	2 (13.33)
Evidence of rodents, insects, or pests	0 (0.00)	15 (100.00)

n= Number of primary health centers, N= frequency.

Table 2: The arrangement of medicines on the shelves of the storage room at pharmacies of PHCs (n=15).

Indicators	Yes	No
	N (%)	N (%)
Are medicines stored directly on the floor?	0 (0.00)	15 (100.00)
Use of racks to keep medicine	15 (100)	0 (0)
Manufacturing dates and expiration dates are clearly visible.	15 (100.00)	0 (0.00)
Separate compartment for expired drugs	6 (40.00)	9 (60.00)
Are medicines stored in a systematic way?	15 (100.00)	0 (0.00)
Are there any expired medicines on the shelves at the time of the visit?	0 (0.00)	15 (100.00)
Drugs on the shelves are arranged with identification labels.	5 (33.33)	10 (66.67)

n= Number of primary health centers, N= frequency.

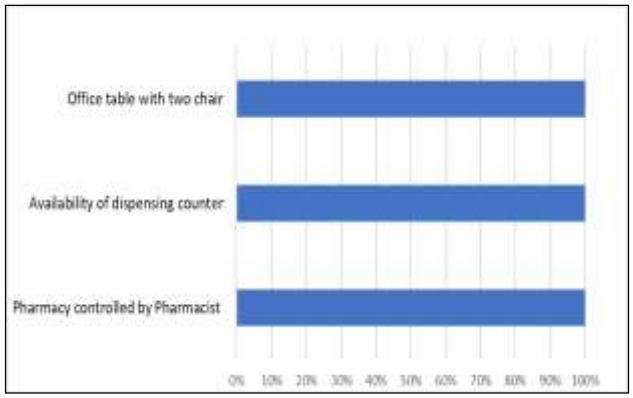

Figure 1: The basic pharmacy infrastructure in PHCs.

Having a pharmacy that is controlled by a pharmacist is essential to ensuring that prescriptions are filled accurately and safely. Pharmacists can not only fill prescriptions, but they can also help customers understand their medications and provide advice on how to take them correctly. The results of the present study show that all pharmacies are controlled and operated by pharmacists. The basic pharmacy infrastructure is shown in Figure 1.

DISCUSSION

The current study highlights the effective implementation of storage conditions for medicines in pharmacies of primary health centers in Gadag Taluk, Karnataka. It was

found that most pharmacies (86.7%) had clean storage rooms, all of which were pest- and insect-free. Most (80%) pharmacies also had a dedicated warehouse, with 100% having methods in place to control temperature and windows that could be opened. Additionally, almost all (93.3%) had cold storage facilities, and all used racks to store drugs; however, only a third (33.3%) arranged drugs with identification labels. Expiration and manufacturing dates were clearly visible in 100% of cases, and 40% had separate sections for expired drugs, all which points to a high level of adherence to established storage guidelines. This is an encouraging result, as the implementation of proper storage conditions is crucial to maintaining the quality and effectiveness of drugs.

The results of the current study clearly demonstrate the need for improvement when it comes to the storage and management of cold chain equipment. Although 93.3% of the PHCs had cold storage facilities, this is still lower than the results from Puducherry and Udupi, where 100% of the PHCs had cold storage.[9,6] This underscores the fact that there is an obvious need to ensure a higher rate of cold storage in all PHCs to ensure the efficacy of the immunisation programme. The lack of cold storage in one PHC can be attributed to the type of PHC and its proximity to the taluk hospital. The absence of cold storage in such a case is highly concerning, as vaccines stored in such conditions may suffer in terms of their efficacy. Therefore, it is essential that greater emphasis be placed on the prevention of heat exposure and contamination of cold chain equipment and that all PHCs be provided with adequate storage facilities. Through this, we can ensure that vaccines are of the highest quality and have the best chances of delivering results. The results of the current study showing that 40% of pharmacies had separate sections for expired drugs are significantly higher compared to Puducherry, where 0% of pharmacies had separate sections for expired drugs, and Odisha, where 20% of pharmacies had separate sections for expired drugs in cold storage.[9,5] This underscores the fact that there is an obvious need to ensure a higher rate of cold storage in all PHCs to ensure the efficacy of the immunisation programme. The lack of cold storage in one PHC can be attributed to the type of PHC and its proximity to the taluk hospital. The absence of cold storage in such a case is highly concerning, as vaccines stored in such conditions may suffer in terms of their efficacy. Therefore, it is essential that greater emphasis be placed on the prevention of heat exposure and contamination of cold chain equipment and that all PHCs be provided with adequate storage facilities. Through this, we can ensure that vaccines are of the highest quality and have the best chances of delivering results. The results of the current study showing that 40% of pharmacies had separate sections for expired drugs are significantly higher compared to Puducherry, where 0% of pharmacies had separate sections for expired drugs, and Odisha, where 20% of pharmacies had separate sections for expired drugs.[9,5] This is even though having separate sections for expired drugs is known to reduce potential health risks as expired drugs may have lost effectiveness or become contaminated. The possible reason for the existence of separate sections for expired drugs being so low in certain areas is due to the pharmacist not feeling the importance of having separate space for expired medicines. To address this, certain health organisations should focus on raising awareness among pharmacists about the potential risks that expired medicines pose and the importance of creating separate sections for expired drugs. This could lead to a higher adoption rate of having separate sections for expired drugs in the long run.

The results of the current study indicate that the manufacturing dates on medicines were clearly visible in all government PHCs (100%), which is a higher percentage than the statement made in the Odisha, report, where manufacturing dates were clearly visible in only 72%.[5] This result is highly promising, as clear visibility of the manufacturing date on medicines is essential for ensuring that the medicine is effective and safe for consumption. By making it visible in all government PHCs, it gives the government an opportunity to make sure that all medicines are of good quality and have not expired or been tampered with in any way. Furthermore, this helps protect patients from any potential adverse effects associated with medicines past their expiration date. The results of the current study show that there is no evidence of rodents in the medicine storerooms of PHCs, which is far better than the results of the survey conducted in Odisha, which reported that 44% of facilities had evidence of rodents.[5] This indicates that the medicine storerooms of PHCs are kept in better hygienic condition than in Odisha, given the potential consequences of rodents infesting medicine storerooms, it is encouraging to see that the current study does not find any evidence of them.[5] It is important to note, however, that these results may not be representative of all PHCs, and so further study is needed to obtain a better understanding of the prevalence of rodents in PHCs across the country. Additionally, further research could explore what strategies the PHCs are utilizing to keep their medicine storerooms free of rodents.

When it comes to controlling temperature, the results from the current study are much better than those in Puducherry and Odisha, which had 0% and 44%, respectively.[9,5] This may be because the PHCS in Gadag Taluk has implemented methods to control temperature, such as air conditioners and fans. The use of these devices has likely helped to bring the temperature in the study location to a more comfortable level. Additionally, other methods, such as insulation and shading, may also have been used to reduce the temperature. This study provides valuable information about the storage conditions of medicines in the pharmacies of primary health centers in Gadag Taluk, Karnataka. The findings suggest that most pharmacies have good storage environments with appropriate control methods in place. However, further research is needed to explore the possible influences of various factors on pharmaceutical storage practices.

One major limitation of the study is that it cannot provide data on the effects of storage conditions on the safety and efficacy of medicines, as this is not within the scope of the research.

CONCLUSION

The assessment of the storage conditions of medicines in pharmacy stores of primary health centers in Gadag Taluk, Karnataka, shows that, overall, the conditions are satisfactory, with most pharmacies having dedicated storage space, a system in place to control temperature, cold storage facilities, and drugs being stored in a systematic way. However, there is still room for improvement in some areas, such as having separate sections for expired drugs and arranging drugs on shelves with identification labels. Overall, it is recommended that pharmacies in Gadag Taluk investigate improving their practices to ensure the quality of medicines is always maintained.

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REFERENCES

1. WHO. Guidelines: Norms and Standards for Pharmaceuticals, 2023. Available at: https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/norms-and-standards-for-pharmaceuticals/guidelines. Accessed 30 May 2023.
2. Proper medicine storage in pharmacies is important, and temperature monitoring is the key, 2023. Available at: https://www.tempgenius.com/proper-medicine-storage-in-pharmacies-is-important-and-temperature-monitoring-is-the-key/. Accessed 1 March 2023.
3. FDA. FDA code of federal regulations title 21, 2023. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm. Accessed 30 May 2023.
4. IPA PHARMA. Codes of pharmaceutical ethics, 2023. Available at https://ipapharma.org/code-of-pharmaceutical-ethics/. Accessed 30 May 2023.
5. Shafaat K, Hussain A, Kumar B, Hasan R, Prabhat P, Yadav V. An overview: storage of pharmaceutical products. World J Pharm Pharm Sci. 2013;2(5):2499-515.
6. Paho.org. Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms, 2023. Available at: https://www.paho.org/hq/dmdocuments/2008/6_Annex_5_report_34.pdf. Accessed 1 March 2023.
7. Indian Public Health Standards (IPHS) Guidelines for Primary Health Centres, 2023. Available at: https://nhm.gov.in/images/pdf/guidelines/iphs/iphs-revised-guidlines-2012/primay-health-centres.pdf. Accessed 11 June 2023.
8. Prinja S, Bahuguna P, Tripathy JP, Kumar R. Availability of medicines in public sector health facilities of two North Indian States. BMC Pharmacol Toxicol. 2015;16:43.
9. NHSR India.org Draft drug stock out assessment, including recommendations for the procurement system, identification of issues arising and mitigation plan, agreed with DHFW, 2014. Available at: https://nhsrcindia.org/sites/default/files/2022-09/NHA%202018-19_07-09-2022_revised_0.pdf. Accessed 30 May 2023.
10. Balakrishnan M, Ganesh J, Veena GKH. Assessment of pharmaceutical store and inventory management in rural public health facilities-a study with reference to Udupi District, Karnataka. Pharm Met. 2015;6(2):53-9.
11. Plus.strathmore.edu. Relationship between effective drug inventory control management and stock-outs in Kenya's public hospitals: A case study of kenyatta national hospital and defence forces memorial hospital, 2016. Available at: http://plus.strathmore.edu/server/api/core/bitstreams/398ecdc4-1860-40c9-85db-de5bf089b8d1/content. Accessed 1 March 2023.
12. WHO. Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products, 2011. Available at: https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs961-annex9-modelguidanceforstoragetransport.pdf?sfvrsn=b80e925f_2. Accessed 30 May 2023.
13. Meena DK, Jayanthi M, Ramasamy K, Thulasingam M. Medicine storage and dispensing facilities in public healthcare pharmacies of Puducherry, India. Cureus. 2022;14(1).
14. Tariq RA, Vashisht R, Sinha A, Scherbak Y. Medication dispensing errors and prevention, 2023. Treasure Island (FL): StatPearls Publishing; 2023.
15. WHO. Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services, 2011. Available at: https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs961-annex8-fipwhoguidelinesgoodpharmacypractice.pdf. Accessed 30 May 2023.

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